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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,694	04/03/2002	Akihiko Sano	0020-4976 P	5505
2292	7590	06/16/2006	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			TRAN, SUSAN T	
PO BOX 747			ART UNIT	
FALLS CHURCH, VA 22040-0747			PAPER NUMBER	

1615

DATE MAILED: 06/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/089,694	<b>Applicant(s)</b> SANO ET AL.	
	<b>Examiner</b> Susan T. Tran	<b>Art Unit</b> 1615	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 March 2006.  
2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 6-12 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 6-12 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn US 6,120,789.

Dunn teaches a non-polymeric sustained delivery system comprising bioactive agent, pore forming agent, controlled release agent, and water-insoluble polymer (see abstract; and columns 2-3). Bioactive agent includes vaccines (column 9, line 27). Pore forming agent includes sodium carbonate (column 7, lines 13-23). Controlled release agent includes acids (column 11, lines 7-64). Dunn further teaches the delivery system is suitable for implantation as a solid matrix (column 6, lines 49-57; and column 12, lines 53-55).

Dunn does not explicitly teach the substance (acids) which reacts with the carbonate in an aqueous solution to generate carbon dioxide. However, where the claimed and prior art products are identical or substantially identical in composition a prima facie case of obviousness has been established. *In re Best*, 562 F.2d 1252, 255, 195 USPQ 430, 433 (CCPA 1977). Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Accordingly, it would have been obvious to one of ordinary skill in the art to prepare a solid matrix having the claimed properties, because Dunn teaches the use of similar components, namely, sodium carbonate and acid in the solid matrix suitable for implantation of vaccines.

Claims 6-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dunn US 6,120,789, in view of Fujioka et al. US 4,985,253.

Dunn is relied upon for the reason stated above. Dunn does not expressly teach the use of silicone polymer.

Fujioka teaches a sustained release composition comprising active core and silicone elastomer as a carrier (column 2, lines 17-27). Thus, it would have been obvious for one of ordinary skill in the art to modify the sustained release solid matrix of Dunn using the silicone elastomer in view of the teaching of Fujioka, because Fujioka teaches an implantable silicone elastomer delivery system that provides a desirable

sustained release rate, because Fujioka teaches silicone elastomer can provide an effective level of release over a long period of time (columns 1 and 2), and because Dunn desires for a delivery system that provides a sustained release rate of bioactive agent.

### ***Response to Arguments***

Applicant's arguments filed 03/30/06 have been fully considered but they are not persuasive.

Applicant argues that the claimed invention is distinct from Dunn because Dunn teaches the use of the additional ingredients, such as pore-forming material to create voids in the composition. However, the transitional phrase "comprises" in the claims does not exclude the additional ingredients.

Applicant argues that the examiner does not explain any motivation to modify Dunn so as to achieve the present invention. In the use of a non-polymeric material for the composition and in stressing the advantage of applying the composition in liquid form, Dunn in fact expressly teaches away from the present invention. Contrary to the applicant's argument, it is noted that Dunn does teach the claimed polymeric carrier. Applicant's attention is called to column 11, lines 35-64, where Dunn teaches the use of water-insoluble polymer as a controlled release carrier that can be dispersed in the composition so that it is embedded within the implant matrix.

Applicant argues that Dunn does not teach a solid composition. In response to applicant's argument that the reference does not show certain features of applicant's

invention, it is noted that the feature upon which applicant relies (i.e., solid composition) is not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, Dunn does teach a solid formulation, note column 12, lines 53-55, teaches the solid implant can also be formed outside the body and then inserted as a solid matrix into an implant site.

Applicant argues that the combination of the secondary reference results in destroying of the operability of the invention of the primary reference. In response to applicant's argument, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Again, as discussed above, the claimed invention does not require the particles to be made of a polymeric material. The only requirement of the polymeric is the carrier. Jujioka is relied upon solely for the teaching of silicone elastomer as a carrier. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Dunn and Jujioka, because Jujioka teaches silicone elastomer can provide an effective level of release over a long period of time (columns 1 and 2), and because Dunn desires for a delivery system that provides a sustained release rate of bioactive agent.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on Monday through Thursday 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', with a long, sweeping horizontal stroke extending to the right.

S. Tran  
Examiner  
Art Unit 1615